

REMARKS

Applicants' Agent wishes to thank the Examiner for examining the above-identified Application. Claims 1, 5-11, and 13-20 are pending in the Application, Claims 1, 5-11, 13-20 have been rejected. The Office Action states firstly: Claims 1, 6-11, 13-20 are pending in the application. Secondly, the body of the Office Action states: "Applicants responses of 10/17/02 and 1/9/02 (Papers 7 and 9) have been entered. Claims 1, 4-11 and 13-20 are pending and under examination." Applicant believes that both instances are transcription errors and that Claims 1, 5-11, and 13-20 are pending.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

This response fully addresses each and every issue raised in the Office Action dated April 2, 2002. Claims 1, 8, and 20, have been amended above, Claim 9 has been cancelled. A detailed discussion of each issue is provided in the sections which follow.

The Examiner's 37 CFR 1.75(I) Objection

Claim 8 has been amended in accord with the Examiner's requirement, and now additionally contains the matter of claim 9.

The Examiner's 35 USC 112 Rejections

The Examiner states that there is no purpose stated in the preamble of claim 1. Claim 1 has now been amended to "particularly point out and distinctly claim" a purpose.

Claims 1 and 8 are rejected because they recite "test site". The term "test site" is defined at page 4 lines 2-3 and claims 1 and 8 have been amended to insert the term "as defined herein".

Claims 1 and 9 are rejected as unclear due to recitation of the term "assessing". This term is defined at page 5, lines 4-5, of the specification and, in addition, would be understood by one of skill in the art. Claims 1 and 8, which now includes the matter of claim 9, have been amended to recite the definition.

The terms "pre-challenge", "concurrent-challenge" and "post-challenge", used in claims 5-6 and 10-11 are clearly defined at page 4, lines 22-30 and one of skill in the art would refer to the specification for their definition.

With regard to the Examiner's rejections of claim 8 and 9, the following applies:

- 1) The purpose of the "study" is now defined in claim 8, Claim 9 has been cancelled.

- 2) the term “control” is defined at page 6, lines 6-23. The term “assess” is discussed above.

The Examiner rejects claims 16-20, as he asserts that it is unclear how the patch of claim 15 would be applied to the cell cultures of claim 16. However, one of skill in the art would understand how such a procedure would be accomplished.

The Examiner asserts that “A” is indefinite in claim 19, but as the term “clinical study” has no antecedent, ‘A’ is required.

Claim 20 has been amended to recite “method”.

The Examiner’s 35 USC 101 Rejection

The Examiner states: “Claims 1-20 (sic) are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. As noted supra in the 112, second paragraph rejection, claims 1 and 8 fail to recite any useful result of the method or study, in that nothing is observed, assessed or measured; and/or nothing is positively concluded from the method.”

Claims 1 and 8 have been amended to clearly recite the purpose of the method or study within the preamble. While the claim has always included such a phrase related to the secondary challenge, the amendment further clarifies the intent of the total method. Support for the amendment can be found at page 3, lines 13-14.

The Examiner’s 35 USC 102 Rejection

The Examiner rejects claims 1, 7-9, and 11 under 35 USC 102(e) as being anticipated by Kapadia et al. (5,935,581). The Examiner states:

“Kapadia et al. show a test/study method in which the skin of mice serves as a ‘responsive system’One week after application of the initiator, at stage 2, the mice are treated with ultraviolet B radiation (twice a week for twenty weeks), which serves as a tumor promoter. This step corresponds to the instant step of “subjecting the test site to a secondary challenge”. This correspondence is clearly correct since the radiation enhances tumor formation initiated by the DMBA.”

However, Applicants are not claiming to have discovered that a secondary insult can, in some circumstances, enhance a result. Rather Applicants are claiming a protocol for specifically enhancing or prolonging a reaction to a primary challenge by means of a secondary challenge. If a researcher wishes to enhance or prolong a reaction, broad guidelines as to methods of doing so are disclosed in the instant specification and claims. There is no disclosure in Kapadia that instructs one of skill, except in the area of tumor formation, as to test method selection.

Further, the Examiner rejects claims 1 and 8 under 35 U.S.C. 102(e) as being anticipated by Fruehauf et al. (6,008,007). The Examiner asserts that Fruehauf, which discloses a method of assessing the synergistic effects of radio-sensitizing/chemotherapeutic drugs and radiation treatments upon isolated cancer cells in wells of a tissue culture plate, discloses the method of the instant application. Again, Applicants are not claiming to have discovered that a secondary insult can enhance a result. Instead, Applicants are providing a means of selecting a method of enhancing or prolong a reaction, caused by a primary insult, by means of selected a secondary insult. There is no such guidance provided by Fruehauf.

CONCLUSION

For the foregoing reasons, Applicants respectfully submit that the Claims as amended are not indefinite nor anticipated in light of the art cited. Accordingly, favorable reconsideration of Claims 1, 5-8, 10, 11, and 13-20 is earnestly solicited in the form of a Notice of Allowance.

Should any issues impeding continuing examination of this Application remain, the Examiner is encouraged to contact the undersigned by telephone at the earliest possible date to achieve a timely resolution.

Respectfully submitted,

For: Tepper et al.



Eileen L. Hughett

Agent for Applicants

Reg. No. 34,352

(513) 626-2127

July 2, 2002

Cincinnati, Ohio 45224

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims

Please amend the following claims:

1. (Twice Amended) A method of enhancing and/or prolonging the response of a primary challenge to a responsive system comprising the steps of:

- a) subjecting a test site, as defined herein, of the [a] responsive system to the [a] primary challenge;
- b) subjecting the test site to a secondary challenge, wherein the secondary challenge differs from the primary challenge and wherein the secondary challenge is designed to enhance, and/or prolong a response of the responsive system to the primary challenge; and
- c) assessing the response;

wherein the primary challenge is a chemical challenge and the secondary challenge is a physical challenge and wherein the term "assessing" means any method of evaluating, observing, noting, and/or comparing the condition (e.g., response) of test sites.

8. (Twice Amended) A study of enhancing and/or prolonging the response of a primary challenge to a responsive system comprising the steps of:

- a) applying the [a] primary challenge to a test site, as defined herein, of the [a] responsive system; applying a secondary challenge to the test site, wherein the secondary challenge differs from the primary challenge and wherein the secondary challenge is designed to enhance and/or prolong a response of the responsive system to the primary challenge, wherein the primary challenge is a chemical challenge and the secondary challenge is a physical challenge; and
- b) creating one or more controls selected from the group consisting of negative controls, primary controls, secondary controls, positive controls, and mixtures thereof;
- c) assessing a primary challenge response subsequent to the primary challenge and prior to the secondary challenge;
- d) assessing one or more secondary challenge responses one or more times after the secondary challenge;

- e) assessing one or more control responses to the controls at the same approximate times as the primary challenge assesment and secondary challenge assessments are made;
- f) drawing conclusions based upon the assessments,
wherein the term "assessing" means any method of evaluating, observing, noting, and/or
comparing the condition (e.g., response) of test sites.

20. The method [clinical study] of Claim 17 wherein the test site is an adult's forearm and the primary challenge is stool.

Please cancel claim 9.